

**REMARKS**

Claims 1-3, 7-11, 16-30, 40, 41, 46-48, 50, 52 and 68-71 are pending in this application. Claims 1, 10, 16, 17, 30, 41, 46, 50 and 71 are amended herein for clarity to more particularly define the invention and are not to be construed as narrowing. New claims 72-102 are added herein. Support for these amendments and new claims is found in the language of the original claims and currently pending claims, as well as throughout the specification, as set forth below. No new matter is added by these amendments and new claims. In light of these amendments, new claims and the following remarks, applicants respectfully request reconsideration of this application, entry of these amendments and new claims and allowance of the pending claims to issue.

Applicants acknowledge that claims 16, 18-23, 25-28 and 68-70 are allowed and that claim 24 is objected to.

**I. Rejection under 35 U.S.C. § 112, second paragraph**

Claims 30 and 71 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to provide proper antecedent basis to certain terms in these claims.

Claim 30 is amended herein to recite a "mixture" rather than a "composition" and claim 71 is amended herein to delete reference to human insulin. Thus, this rejection has been overcome and applicants respectfully request its withdrawal.

## **II. Rejection under judicially created doctrine of obviousness-type double patenting**

A. Claims 1-3, 7-11, 17, 29, 30, 40, 41, 46-48, 50 and 52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-142 of copending application no. 10/235,381 (Attorney Docket No. 9233.68).

B. Claims 1-3, 7-11, 17, 29, 30, 40, 41, 46-48, 50 and 52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-230 of copending application no. 10/075,097 (Attorney Docket No. 9233.46).

As the Examiner has acknowledged, these rejections are provisional rejections because none of the claims of these co-pending applications have yet been allowed. Applicants respectfully request the withdrawal of these rejections on this basis, with the understanding that, should claims issue in either of these applications before allowable subject matter is identified in the present application, applicants will address this double-patenting issue at that time.

## **III. Rejection under 35 U.S.C. § 102(e)**

Claims 1-3, 7-11, 17, 29, 30, 40, 41, 46-48, 50 and 52 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Ekwuribe et al. (U.S. Pub. No. 2003/0050228), on the basis that this publication teaches monodispersed mixtures of an insulin drug-oligomer conjugate where the oligomer is  $C(=O)-(CH_2)_5-(OC_2H_4)_7-OCH_3$  attached at Lys B29. The Office Action states that this is 102(e) art against the instant claims because this publication claims priority to a provisional application filed February 15, 2001 and the inventorship is different.

The Ekwuribe et al. publication is not available as 102(e) art against the pending claims because the subject matter upon which the Examiner relies in the publication and the subject matter of the rejected claims was invented by the same inventors. Applicants provide herewith a Declaration under 37 C.F.R. § 1.132 signed by co-inventor, Dr. Nnochiri N. Ekwuribe, stating that the inventors are the same. Applicants previously provided a draft of this Declaration to the Examiner for review and were told by the Examiner that submission of this executed Declaration is satisfactory to demonstrate that the inventorship is the same and to overcome this rejection, which applicants respectfully request.

Applicants also wish to point out that it is stated in paragraph 2 of the Declaration that the three additional coinventors have been added to application serial number 10/075,097. In fact, as of the submission of this Amendment, the Request to Correct Inventorship has not yet been submitted to the PTO, but will be filed shortly. Upon request from the Examiner, applicants will provide documentation of this submission in the '097 application.

#### **IV. Rejection under 35 U.S.C. § 103**

A. Claims 1-3, 7-11, 17, 29, 30, 40, 41, 46-48, 50 and 52 are rejected under 35 U.S.C. § 103 are allegedly being obvious over Radha Krishnan et al. in view of Delgado et al. and PCT publication WO 97/14740.

B. Claims 1-3, 7-11, 17, 29, 30, 40, 41, 46-48, 50 and 52 are rejected under 35 U.S.C. § 103 are allegedly being obvious over Radha Krishnan et al. in view of Delgado et al. and PCT publication WO 97/14740 and further in view of Harris et al.

The Office Action states that applicants' previously submitted Katz-type Declaration by Dr. Radhakrishnan was not sufficient to show that the Radha Krishnan et al. article is not by another and therefore unavailable as prior art under 35 U.S.C. § 102(a) as applied in the above rejections under 35 U.S.C. § 103. The Office Action explains that the problem with the Declaration is the omission of Amy Odenbaugh as a co-inventor in the Declaration.

Applicants provide herewith a revised Katz-type Declaration, executed by Dr. Radhakrishnan, which includes Amy Odenbaugh as a co-inventor and an explanation that she is not a co-author on the Radha Krishnan et al. article, as requested by the Examiner. The omission of her name from the previously submitted Declaration was an inadvertent typographical error and applicants apologize for any confusion resulting from this error. The currently submitted Katz-type Declaration corrects this defect and properly demonstrates that the Radha Krishnan et al. article is not by another and is therefore not available as prior art under 35 U.S.C. § 102(a) or 35 U.S.C. § 103. Applicants previously provided a draft of this revised Declaration for review by the Examiner and were told by the Examiner that this revised Declaration is satisfactory to remove the Radha Krishnan et al. reference as 102(a) art and to overcome this rejection, which applicants respectfully request.

#### **V. New claims 72-102**

New claims 72-102 are added herein, which recite substantially monodispersed and monodispersed mixtures having the various embodiments of this invention. Support for these new claims is found in the language of the original and pending claims and at least in the specification on page 9, lines 5-9, wherein the terms "substantially monodispersed" and "monodispersed" are defined. No new matter is added by these new claims and the subject matter of these claims is believed to be free of the prior art for the same reasons presented for the

currently pending claims. Thus, applicants request entry of these new claims and their allowance to issue.

**VI. Filing of Request for Continued Examination in pending application serial number 09/873,731**

Applicants provide herewith a copy of a Request for Continued Examination filed on August 25, 2003 in the above-referenced application for the Examiner's reference. Specifically, this referenced application was the subject of a provisional obviousness type double patenting rejection of claims 59-67 in the February 24, 2003 Office Action. To address this rejection, applicants provided a copy of a Request for Continued Examination filed on April 10, 2003 as evidence that, although a Notice of Allowance had been issued on February 21, 2003, the case had been withdrawn from allowance, thereby obviating any double patenting rejection. As the Examiner is probably aware, a second Notice of Allowance was issued on June 10, 2003 for application number 09/873,731 and applicants again provide evidence that the case is withdrawn from allowance at this time.

**VII. Recordation of Interview Summary in accordance with M.P.E.P. § 713.04**

Applicants wish to make of record the Interview Summaries prepared and submitted by Examiner Russel on July 16, 2003, July 24, 2003 and August 13, 2003, respectively. Applicants concur that these Interview Summaries accurately reflect the substance of the telephone interviews of July 2, 2003, July 18, 2003 and August 12, 2003, respectively.

Attorney Docket No. 9233.54  
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Filed: June 4, 2001  
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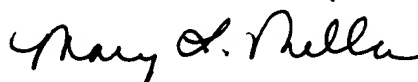
### VIII. Supplemental Information Disclosure Statement

Applicants plan to submit shortly a supplemental Information Disclosure Statement (IDS) in accordance with 37 C.F.R. 1.97(c)(2), along with the requisite fee. Applicants request that the documents disclosed on this IDS be made of record in this application.

The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue.

A check in the amount of \$84.00 for additional claim fees is enclosed. This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



Mary L. Miller  
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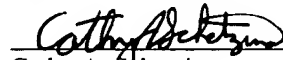
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Cathy A. Schetzina